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10/593,530	09/18/2006	Janel Birk	18006 US PCT (HEA)	4476
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ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
EXAMINER				
STRANSKY, KATRINA M				
ART UNIT		PAPER NUMBER		
3734				
NOTIFICATION DATE		DELIVERY MODE		
06/23/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents\_ip@allergan.com

# Office Action Summary

## Application No.

10/593,530

## Applicant(s)

BIRK ET AL.

## Examiner

KATRINA STRANSKY

## Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 10-14, 19, 20 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-14, 19, 20 and 35-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This action is entered in response to Applicant's Amendment and Reply of April 27, 2011. Claims 1, 10, 12, 13, 35, 37, 41 are amended. Claims 5, 8-9, 15-19 and 21-34 are canceled. Claims 42-47 are newly added. Claims 1-4, 6, 7, 10-14, 19, 20 and 35-47 are pending.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wazne, US Publication No. 2003/0158569 A1.
3. Regarding claim 1, Wazne discloses a gastric balloon (1, Fig. 5) comprising: a shell (3, Fig. 5); a receiver formed in said shell (6, Fig. 5) having a recessed region in the shell (recessed area of balloon 3, as shown in Fig. 5); a valve (return valve 4, Fig. 5) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (7, Fig. 5) housed in the recessed region of the receiver and configured to be withdrawn from the recessed region of the receiver and extendable from the stomach of a patient to the mouth of the patient wherein said shell is inflated

and deflated from outside the body of the patient via said retractable tubing (See Fig. 5, paragraph [0042]; and paragraphs [0065] to [0066]).

4. Regarding claim 4, Wazne discloses that the retractable tubing is fluidly connected to the shell via an interface (10, see Fig. 5).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-3 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Mouri et al, US Patent No. 6,074,378.

7. Regarding claims 2-3 and 10, Wazne discloses the claimed invention except for the retractable tubing is formed in one or more spirals or in a coil. However, Mouri et al disclose a self retaining catheter (10) comprising a catheter body (11) having a lumen and made of a shape memory material (col. 5, lines 52-55). The catheter body (11) has a shape memory coil wire (14) buried inside of it (col. 5, lines 66-67 and col. 6, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (12) of Wazne with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (col. 2, lines 29-34).

8. Regarding claims 11-13, Wazne lacks the teaching of that the retractable tubing is made of a material having a memory, a soft material comprising a radial spring, a semi-rigid material having a memory, and a shape memory alloy. However, Mouri et al. also teach that the catheter (11) may be formed from is formed of a soft material (urethane, col. 5, line 53), a semi-rigid material (shape memory alloy, Col. 5, line 55), or a shape-memory alloy to return the tubing to the proper shape (shape memory alloy, col. 5, line 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (12) of Wazne with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (Mouri et al, col. 2, lines 29-34).

9. Claims 6-7, 14 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Gau et al, US Patent No. 5,084,061.

10. Regarding claims 6-7 and 14, Wazne discloses the claimed invention except for a receiver that is a molded valve patch bonded to the shell. However, Gau et al. disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system

of Gau et al. to the receiver of Wazne in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

11. Regarding claims 35-36 and 43-44, Wazne discloses a gastric balloon (1, Fig. 5) comprising: a shell (3, Fig. 5); a receiver formed in said shell (6, Fig. 5) having a recessed region in the shell (recessed area of balloon 3, as shown in Fig. 5); a valve (return valve 4, Fig. 5) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (7, Fig. 5) housed in the recessed region of the receiver and configured to be withdrawn from the recessed region of the receiver and extendable from the stomach of a patient to the mouth of the patient wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (See Fig. 5, paragraph [0042]; and paragraphs [0065] to [0066]). Wazne lacks the teaching of a molded valve patch bonded to the shell. However, Gau et al. disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube that is bonded to the molded valve patch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al. to the receiver of Wazne in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

12. Claims 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne and Gau et al as applied to claim 35, and further in view of Duffy, US Publication No. 2005/0171568 A1.

13. Regarding claims 42 and 45, Wazne and Gau et al do not expressly disclose an axle that resists withdrawal of the retractable tubing from the axle. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Wazne as modified by Duffy, the torsionally loaded axle can be located horizontally or vertically with respect to said receiver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the receiver of Wazne as modified by Gau such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Wazne, after the balloon is inflated (Duffy, paragraph 0032).

14. Claims 41, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Cheng, US Patent No. 4,693,695.

15. Regarding claims 41, 46 and 47, Wazne discloses a gastric balloon (1, Fig. 5) comprising: a shell (3, Fig. 5); a receiver formed in said shell (6, Fig. 5) having a recessed region in the shell (recessed area of balloon 3, as shown in Fig. 5) that forms

a small diameter portion of the shell (the smallest diameter of shell 3 is at the recessed region, see Fig. 5); a valve (return valve 4, Fig. 5) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (7, Fig. 5) housed on the small diameter portion of the receiver and configured to be withdrawn from the small diameter portion of the receiver and extendable from the stomach of a patient to the mouth of the patient wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (See Fig. 5, paragraph [0042]; and paragraphs [0065] to [0066]). Wazne also discloses an interface (10, Fig. 5) on the small diameter portion to allow fluid to enter or exit the balloon; and that the tubing is coupled to the interface (Fig. 5). Wazne lacks the teaching that the receiver divides the shell substantially into two hemispheres; that the tubing is wrapped around the small diameter portion and the small diameter portion is an indentation that extends around the shell. However, Cheng discloses a balloon (12) having a receiver (42) forming a small diameter portion of the shell, which divides the balloon into two hemispheres (18/20) and houses a retractable tether (14) (Figs. 4-5) on a small diameter portion of the receiver where the retractable tubing is wrapped around the small diameter portion of the balloon and the small diameter portion extends entirely around the balloon (Figs. 4-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the balloon of Wazne with two hemispheres connected by a receiver that provides fluid communication to both hemispheres as disclosed by Cheng, such that the retractable tubing (12) is in fluid communication with the receiver,



in order to provide a means for decreasing the profile of the tubing once the gastric balloon reaches the gastric lumen.

16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Adams, US Publication No. US 2002/0183765 A1.

17. Wazne disclose the claimed invention except for wherein said valve is a slit valve. However, Adams discloses a slit valve (104) contained in an inflation lumen (104) used to inflate a balloon (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Wazne with the slit valve of Adams in order to permit passage of the balloon inflation fluid in one direction only (Adams, Para [0077]).

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Trick, US Patent No. 4,417,567.

19. Wazne discloses the invention as claimed except wherein said valve is a septum. Trick discloses a balloon (18) having an elongated stem which is closed with a septum (24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Wazne with the septum of Trick in order to allow inflation fluid to be added to or removed from the inflation tube leading to the balloon by a hollow needle (Trick, Col. 2, lines 64-68, and Col. 3, lines 1-2).

20. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wazne in view of Duffy, US Publication No. 2005/0171568 A1.

21. Regarding claims 37-40, Wazne discloses a gastric balloon (1, Fig. 5) comprising: a shell (3, Fig. 5); a receiver formed in said shell (6, Fig. 5) having a recessed region in the shell (recessed area of balloon 3, as shown in Fig. 5); a valve (return valve 4, Fig. 5) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (7, Fig. 5) housed in the recessed region of the receiver and configured to be withdrawn from the recessed region of the receiver and extendable from the stomach of a patient to the mouth of the patient wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (See Fig. 5, paragraph [0042]; and paragraphs [0065] to [0066]). Wazne lack the teaching of a torsionally loaded axle structured to retract said retractable tubing into the receiver, where the receiver has a longitudinal axis and the torsionally loaded axle is substantially aligned along the longitudinal axis or substantially perpendicular with the longitudinal axis.

22. However, Duffy teaches a torsionally loaded axle (26, Fig. 6), wherein the torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing (paragraph 0032); and the torsionally loaded axle includes a pre-grooved surface (18, Fig. 6) for accommodating said retractable tubing. In the receiver of Wazne as modified by Duffy, the torsionally loaded axle can be located along the longitudinal axis or substantially perpendicular to the axis of the receiver. It would have been obvious to one having ordinary skill in the

art at the time the invention was made to make the receiver of Wazne such that the tubing (12) is accommodated by the wheel and the axle of Duffy in order to provide a means retract the tubing (12) into the receptacle of Wazne, after the balloon is inflated (Duffy, paragraph 0032).

### ***Response to Arguments***

23. Applicant's arguments with respect to claims 1, 35, 37 and 41 have been considered but are moot in view of the new grounds of rejection.

### ***Conclusion***

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA STRANSKY whose telephone number is (571)270-3843. The examiner can normally be reached on Monday thru Friday, 8:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KS/  
Examiner, Art Unit 3734

/Gary Jackson/  
Supervisory Patent Examiner, Art Unit 3734  
June 17, 2011